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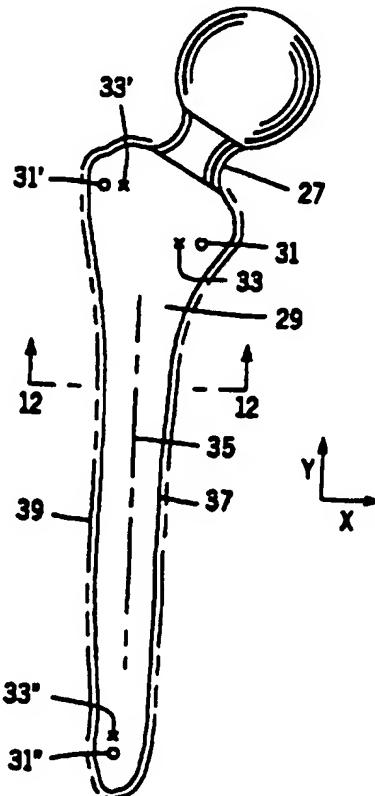
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(54) Title: METHOD FOR PERIPROSTHETIC BONE MINERAL DENSITY MEASUREMENT

(57) Abstract

A method of evaluating bone density around a radiolucent composite prosthesis (27) establishes an implant boundary (118, 124) by fitting a stored template to radio-opaque reference markers (31) embedded in the prosthesis. The implant boundary is used to create a measurement boundary (126) displaced from the implant boundary toward the bone (26) producing a conformal region of interest. Matched histograms (130) of bone density in a lateral and medial region of interest may be displayed to evaluate symmetrical stress defects. Alternatively, bone density may be displayed plotted along an axis (132) cutting across the medial and lateral sides. Fiducial points (100, 102, 104, 106, 108, 110) are identified from the bone and implant morphology to ensure that either display will have a repeatable reference, and hence that such displays will be directly comparable to later and earlier displays thereby aiding in the detection of bone change.



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**METHOD FOR PERIPROSTHETIC
BONE MINERAL DENSITY MEASUREMENT**

This application is a continuation-in-part of U.S. application 08/073,264, filed June 7, 1993, which is a continuation of U.S. application 07/862,096, filed April 2, 1992, which is a continuation of U.S. application 07/655,011, filed February 13, 1991.

Field of the Invention

The present invention relates to the field of radiographic analysis of the human body and, in particular, to a method of measuring and displaying bone mineral density adjacent to prosthetic bone implants.

Background of the Invention

Bone prostheses are commonly provided to patients having bone disease or injury. Such prosthetic devices are manufactured of durable materials such as metals, ceramics, or dense plastics, and are attached to the remaining bone to replace the function of defective or missing bone and joint. In a hip replacement, for example, the ball-shaped head of a femur may be replaced with a prosthetic ball attached to the proximal end of the femur by a shaft fitted within the femur shaft.

The loosening of such implants over time and with use is a significant concern. Many different techniques have been employed to try prevent such loosening. Examples include cementing the implants to the bone, the use of porous coatings on the implant to stimulate bone in-growth,

and custom fit implants.

A good fit between the implant and the bone will impart a pattern of stress onto the bone which may cause it to regenerate. If the bone grows adjacent to the implant there will be less chance of loosening.

Alternatively, loss of bone around the implant may indicate poor fit between the bone and implant in certain areas and provide an early indication of future loosening or failure of the implant. For this reason, the implanted bone is often monitored after the implant is surgically implanted. Such monitoring may be performed by conventional radiographic studies, however large changes in bone density of up to 30% may be necessary before such changes become apparent on the radiograph. Preferably, digital radiographic techniques are used to provide a quantified measurement of bone density. Such techniques include dual energy x-ray absorptiometry ("DEXA") in which a measurement of bone mineral density is derived from the varying absorption of the bone of x-rays at different energies, and dual photon absorptiometry ("DPA") where a similar measurement is made using radioisotopes. Such densitometers provide quantitative *in-vivo* measurement of bone mineral density ("BMD"). Other digital radiographic techniques such as computed tomography ("CT") may also provide measurements of bone density, however, the metal of the prosthesis may create image artifacts in a CT image rendering the measurement of

bone density in the neighborhood of the prosthesis problematic.

Conventional DEXA or DPA equipment, when used to monitor changes in bone density, may obscure subtle changes of the bone near the implant. The region of interest ("ROI") that is isolated and evaluated by such equipment may include irrelevant bone, tissue and other artifacts. Further, the ability to determine bone loss over time is limited, with such equipment, because of the difficulty in matching the data between two different measurement periods.

Recently there has been increased interest in implants constructed of composite materials, such as carbon fibers and various matrix materials, having less stiffness than the ceramic and metal materials presently used. An implant whose flexibility more closely matches that of the bone in which it is implanted is thought to eliminate "stress shielding" in which the bone around the implant is shielded from normal stresses, and thus benefit from the effects of such stress in bone remodeling and bone strengthening. A flexible implant, in contrast to stiffer implants, may pass stress through to the surrounding bone.

Many composite materials considered for implants are essentially transparent to x-rays making it difficult to accurately locate the interface between the bone and the implant for post-operative evaluation of the fit of the implant and the health of the surrounding bone.

Summary of the Invention

The present invention provides a method of reproducibly evaluating bone density measurements in a region of interest conforming to the interface between a radiolucent implant and neighboring bone.

Specifically, a matrix of bone density data values is analyzed to identify the location of radio-opaque reference markers embedded in the implant. A stored template, having stored reference marker data, is fit to the location of the reference markers and provides a template edge used to deduce an implant boundary within the matrix of data values. A measurement boundary translated from the implant boundary by a predetermined distance along a translation axis is then determined and bone mineral density within a plurality of segments following the path of the measurement boundary are calculated. A plot of segment values versus distance along the implant boundary is then displayed.

One object of the invention, therefore, is to provide an accurate indication of the state of the bone immediately adjacent to the implant. The use of a conforming ROI prevents bone from outside of the implant area from influencing or obscuring the measurements of bone near the implant. The result is improved sensitivity and easier measurement. The use of a template allows accurate determination of the implant edge, preventing the bone measurement from being influenced by inclusion of the low

density implant.

Another object of the invention is to provide a readily reproducible measurement that may be compared to other later studies. Fiducial points may be established with respect to the bone and the implant to form a reference for the plot of bone density. The conforming ROI is referenced from the edge of the implant and the fiducial points and therefore may be accurately and repeatably located.

Plots of bone density showing the medial and lateral sides of the implant aligned in the proximal/distal direction also may be displayed simultaneously.

Yet a further object of the invention, then, is to provide a display method that highlights possible implant related bone resorption. With the medial and lateral sides of the bone measured and displayed simultaneously, symmetrical or non-symmetrical bone loss is readily apparent, such as may be caused by abnormal stress patterns from the implant.

Other objects and advantages besides those discussed above shall be apparent to those experienced in the art from the description of a preferred embodiment of the invention which follows. In the description, reference is made to the accompanying drawings, which form a part hereof, and which illustrate one example of the invention. Such example, however, is not exhaustive of the various alternative forms of the invention, and therefore reference is made to the

claims which follow the description for determining the scope of the invention.

Brief Description of the Drawings

Fig. 1 is a schematic view of a dual x-ray bone densitometer suitable for collecting bone density data over a scan for use with the present invention;

Fig. 2 is a flow chart showing the steps of separating tissue, bone, and implant and identifying fiducial points in the collected data;

Fig. 3 is a flow chart showing the steps of the "identify implant" step from the flowchart of Fig. 2;

Fig. 4 is a flow chart showing the steps of the "identify bone" step from the flowchart of Fig. 2;

Fig. 5 is an illustration of the location of the landmarks in the femur and implant used in the process of Fig. 2;

Fig. 6 is a flow chart showing the steps of creating a histogram of bone density;

Fig. 7 is a flow chart showing the steps of creating a trans-prosthetic profile of bone density;

Fig. 8 is a pictorial representation of a screen display of a bone density image together with a periprosthetic histogram;

Fig. 9 is a pictorial representation of a screen display of a bone density image together with a trans-prosthetic profile;

Fig. 10 is an anterior/posterior view of a composite implant for a femur showing a template edge derived from the implant, the location of radiopaque reference markers forming stored reference marks of a template including the template edge, and measured reference mark positions to which the template may be fit;

Fig. 11 is a flow chart showing the steps of employing the template of Fig. 10 in creating an implant boundary; and

Fig. 12 is a simplified cross-sectional view of the implant of Fig. 10 taken along lines 12-12 showing the effect of rotation of the implant on the relative spacing of the reference markers.

Detailed Description of the Preferred Embodiment

The present invention provides the ability to analyze *in vivo* bone mineral density within one or more regions of interest, or ROI, that conforms to the outline of the prosthesis implanted into a patient. This flexibly defined ROI, which will thus not normally be rectangular, permits critical areas of bone density to be examined free from influence by other areas and structures. The ROI may also be referenced to a fiducial point, to permit the same ROI to be evaluated by repetitive scans taken over long periods of time to generate reliably comparative values.

The values obtained from bone density measurement in the ROI may be displayed in a histogram of average or cumulative bone density values taken within a series of

segments along the implant. The display of such a histogram on a CRT screen can provide to the clinician an instantaneous picture of bone density over the length of the implant. Alternatively, a profile of bone density along an individual segment may be examined to make a quantitative measurement of bone adsorption or hypertrophy in the neighborhood of the bone. Both medial and lateral histograms and profiles may be displayed simultaneously to permit the rapid identification of symmetrical effects that may indicate their origin in stress or lack of stress from the implant.

Instrument

Referring to Fig. 1, a bone densitometer 10, of the preferred type for use with the present invention, projects a dual-energy x-ray beam 12 from a x-ray source 14 along a ray 16 through a patient 18 to an opposed detector 20. The x-ray source 14 and detector 20 are mounted on a carriage 22 to move in unison in a raster scan pattern 24 by means of stepper or servo motor (not shown). The raster scan pattern 24 sweeps the ray 16 over a rectangular area of the patient 18 by alternately directing it along one of two perpendicular axes x, and y of a Cartesian coordinate system with the x-ray beam 12 parallel to a third orthogonal z-axis.

Preferably, in the case of the evaluation of a hip implant, the carriage 22 is positioned to sweep an area including the neck and shaft of the femur 26, including the

trochanter, and prosthetic implant 27. The orientation of the raster scan pattern 24 is preferably such that the shaft of the femur 26 lies substantially parallel to the y-axis of the raster scan and the data is acquired in successive scan lines along the x-axis. The scanning, data analysis, and data display procedures described here may also be performed on prostheses in other parts of the body in which case the orientation, location and length of the raster scan may be suitably adjusted.

The movement of the carriage 22 is controlled by a motor controller 28 receiving signals from a computer 30. The x-ray source 14 includes an x-ray tube along with a K-edge filter to create two narrow energy bands of x-ray emissions. The signal from the detector 20 is sampled and digitized by data acquisition system ("DAS") 34 which may transmit the digitized samples to the computer 30 which stores the data in computer memory (not shown) or on mass storage device 36. An operator may provide inputs to the computer 30 by means of keyboard 38 and trackball 40 (or mouse) which allow positioning of a cursor on display screen 42 as is understood in the art. The display screen 42 also provides a means of displaying information obtained from the raster scan.

At a continuous series of discrete data points over the raster scan pattern 24, the signal from the detector 20 is sampled by the DAS 34 at each of two x-ray energy levels

produced by the x-ray source 14, as filtered by the K-edge filter. Thus at each location, two samples, having values corresponding to the absorption by the patient 18 of x-rays 12 at both of the x-ray energy levels, may be collected. Each pair of samples may be identified to the x and y coordinate of the location at which the samples were acquired. Together, the sample pairs over the entire raster scan pattern form elements of a data matrix, whose matrix coordinates correspond to the ray 16 coordinates. On presently available DEXA machines, as shown in Fig. 1, a spatial resolution of 0.6 mm between samples may be obtained over a raster scan area of about 12 by 14 cm.

Referring to Fig. 2, the acquisition of this data matrix is represented by process block 50. As is understood in the art, the sample pair taken at each of the two energy levels together provides an indication of bone density or mineral content of the bone along ray 16. The data matrix therefore represents the density of the tissue and bone over the scanned area of the patient's femur 26. It will be understood to one of ordinary skill in the art that the data matrix of bone density samples also may be obtained by other densitometers, such as those based on DPA and CT as described above. The data matrix is stored in a file on computer 30.

Image analysis

Upon completion of the acquisition of data matrix, the

data elements of the matrix are analyzed to differentiate data elements associated with bone from data elements associated with tissue and the implant. This process is illustrated by the flow chart of Fig. 2, illustrating the process of image analysis, which begins with the step of acquiring the matrix of data values from the scan of the patient. Included within this step, indicated at 50 in Fig. 2, is the combining of the two values of each sample to create a non-calibrated value corresponding to the total density along the associated ray 16 of each sample. The data points thus created are referred to as PBM, for pseudo bone mineral content. The numbers are pseudo values because they are non-calibrated and therefore dimensionless. At this point in the analysis, therefore, only the relative differences between the data points are significant, not their absolute values. While the calibration for each value could be done at this point, it is consumptive of computer resources, and thus is deferred at this point, and the PBM values are used. The calibration of the final values to correspond to standard physical values is performed as a last step. This technique is well known in the art.

The remaining steps in the flowchart of Fig. 2 will be described first in overview and then in detail. The data values of PBM are processed at step 52 or a template is used to identify the implant. Then at step 54, the values are analyzed again to identify the bone. At step 56, the bone

values are again analyzed to identify the bone landmarks. Based on that analysis, the regions of interest in the bone are identified at step 58. From the analysis of those regions, baselines are derived at step 60. Finally the results are calculated and calibrated and the results are displayed at step 62.

Identify Implant

This process is intended to identify regions of the data matrix of PBM values which correspond to the physical implant. Since the values are at this point dimensionless, the analysis of the values to determine the values which correspond to the implant must be done on the basis of relative comparison of values rather than absolute values. To begin the process, which is illustrated in Fig. 3, the matrix of data values is filtered with a low band pass filter to remove high frequency noise components from the data at step 70. Next the data values must be analyzed to generally identify the area of the implant.

Metal and Ceramic Implants

Expressed in absolute values, the normal biological range of bone mineral density in human femurs ranges up to values less than 3.0 grams per square centimeter. An examination of the density values of common hip implants reveals that most metal and ceramic implants have a density value much greater than 3.0. Thus, working with the PBM data matrix, a comparative analysis is performed to identify

a region where the values are abnormally high when compared to other parts of the data matrix. This step is illustrated at 72 in Fig. 3, which illustrates the procedure for the implant identification step 62 of Fig. 2. This analysis results in the generation of a threshold value, above which all data points are defined to represent implant, and those data values are tagged by the computer as representing implant.

The next step is to fill any voids or defects in the representation of the implant. For some implants, the matrix of data values has been found to have occasional values inside the area of the implant with inappropriately low PBM values. At step 74, all data points that are surrounded on all four sides within a defined distance (5mm) by implant are also defined to be implant. This step has the effect of filling in a solid area in the matrix as implant area. The edges of the implant area are then adjusted at step 76. The absolute edges of the implant are identified by locating the points in the data matrix at which the greatest differences exist between adjacent values. These points of greatest change are defined to be the edge of the implant. This calculated true edge is slightly extended outward in this step to compensate for shadowing or partial edge effects caused by the sharp edge. This is done by moving the defined edge outward until the change between adjacent data point values becomes almost

zero. At this step in the process a rough outline of the implant exists in the matrix of values.

It is now possible to smooth out the rough outline of the implant created to this point. This step, indicated at 78 in Fig. 3, involves breaking up the identified edges of the implant into a series of small sections which are defined between "nodes." The nodes are defined to be the locations of changes in direction of the implant perimeter, such as corners. Since presently used implants are known to have certain shapes, certain nodes can be "forced" onto the data, since the system knows that a discontinuity exists in the real implant at a certain point. Then between each set of nodes thus defined a best fit curve routine is used to find a high order (fourth degree) curve which will have a best fit with the measured data to define the edge of the implant. The curves that best represent the data are then incorporated into the final outline of the implant at step 80.

Once the outline of the implant is derived, all data point values in the matrix of data points inside the curve thus defined are defined and tagged to be implant, at step 82. This, in essence, isolates all the implant values from the values derived from the areas of soft tissue and bone. The values thus defined as implant are then highlighted for the ultimate display at step 84 and are excluded from further data analysis to save processor time. A manual

override is provided so that correction for misapplication of the implant defining procedure can be implemented by the operator if necessary.

Composite Implants

When the implant 27 is a composite material rather than a metal or ceramic, the comparative analysis described above in which the implant 27 is distinguished from surrounding bone by establishing a threshold of PBM values is unsuccessful. The PBM values of the composite implant 27 are generally lower than or equal to the bone itself.

Nevertheless, the composite implant may not simply be ignored in the calculation of bone quality near the implant. It is important to isolate the implant from the measurements of the bone for a number of reasons. First, the implant edge serves as a reference to ensure the same region of interest is being measured when a series of measurements are made spanning a year or more. Second, determining the implant edge allows the region of interest to be on the critical bone implant interface area. An overly inclusive region of interest may obscure small changes in this important interface area. Third, exact identification of the edge of the implant prevents calculations of average bone density from being diluted by over-inclusion of low PBM implant data.

Thus, an alternative method is adopted for determining the implant boundary if the implant is a composite material,

as identified by the operator through the keyboard 38 of the bone densitometer 10.

Referring to Fig. 10, radiopaque tantalum marker beads 31 or other reference markers may be placed in the shaft 29 of the implant 27 to provide data as to the location of the implant, such as may be detected in radiographic examination of the implant 27. The marker beads 31 are embedded in the surface of the shaft 29 so as to be removed from regions of contact with bone and tissue.

Two marker beads 31 and 31' may be placed at the proximal end of the shaft 29 on the medial and lateral sides respectively. A third bead 31" may be placed at the distal end of the shaft 29. Thus, for an anterior/posterior radiographic image of the implant 27, three reference markers 31, 31' and 31" should be separately visible.

Ideally, the distal reference marker 31" will be generally along the axis 35 of symmetry of the shaft 29 with reference markers 31 and 31' being displaced equally on either side of the axis 35 to provide an indication of any rotation about axis 35.

The dimensions of the implant 27 and the coordinates of the medial and distal edges, 37 and 39 respectively, of the shaft 29, are stored as a numerical template to be accessible by computer 30. The template is formed of a set of coordinate points, representing the edges 37 and 39, referenced to coordinate points of the centers of the

reference markers 31, 31' and 31". Accordingly, once the position of the reference markers 31, 31' and 31" are identified within the matrix of acquired data, the particular matrix elements along the medial and distal edges, 37 and 39, may be rapidly identified.

Referring also to Figs. 2 and 11, step 52 of identifying the implant 27 data, in the case of composite implants, begins with the identification of the reference markers 31 shown as process block 85. The identification of the reference markers 31 may be done simply by manually locating a cursor within an image of the implant 27 where the reference markers 31 will be visible as small circles of high contrast.

Alternatively, the high contrast reference markers 31 may be readily identified by the same thresholding procedure used to identify metallic implants. That is, a comparative analysis is performed of the PBM data matrix to identify small clusters of data values where values are abnormally high when compared to other parts of the data matrix. In the event that more than three areas are identified with such high PBM values, areas having an exact number of data values equal to the known size of the reference markers 31 are preferentially selected.

The center of mass of the each of the qualifying data values is selected as the coordinates of the corresponding reference markers 31.

Next, as indicated by process block 86, stored reference marks 33, 33', 33", corresponding to reference markers 31, 31', and 31", forming part of the template accessible by the computer 30, are fit to the measured reference marks 31. This fitting involves incrementing or decrementing the coordinates of each of the stored reference mark 33, 33', and 33", until the cumulative separation between the measured reference markers 31, 31', and 31" and the stored template reference markers 33, 33', and 33" is minimized as represented by the sum of the square of the absolute differences. This procedure has the effect of shifting the template over the measured values until a best fit (without rotation) is realized.

This translatable best fit procedure is followed by a rotation of the axis 35 of the template on the measured data, again with an eye toward reducing the sum of the magnitude of the distances between the measured reference marks 33, 33', and 33" and the actual reference marks 31, 31', and 31" within the data matrix.

This process of translating the template with respect to the data matrix and rotating the template with respect to the data matrix is repeated for a predetermined number of iterations after which the template and actual data should be accurately aligned in a best fit. If the difference between the measured markers 31, 31', and 31" and the markers 33, 33', and 33" of the template is greater than a

predetermined error value, a signal is provided to the operator indicating a possible problem with matching the data such as may be caused by misidentification of the proper template to be used, or artifacts within the image that were mis-identified as reference markers.

If the difference between the actual measured reference markers and the reference markers of the template is less than the predetermined error value, the program proceeds to process block 87 and the data of the data matrix is marked to indicate which data values are of implant 27 as opposed to the bone. This step provides a tagging of all the data point values in the matrix of data points inside the implant essentially identical to that of step 84 previously described. Again, a manual override is provided so that correction for misapplication of the implant to filing procedure can be made by the operator.

Referring to Fig. 12, in a further embodiment multiple templates may be stored or generated by computer 30 for each implant 27, each template providing a projection of the implant 27 at slightly different angles of rotation about the implant axis 35. New medial and lateral boundaries 37' and 39' may be generated based on the projection of the rotated implant 27 on the image plane.

After the best fit process of process block 87, remaining deviation between the measured reference markers 31, 31' and 33' and the template reference markers 33, 33'

and 33° is interpreted as rotations of the implant 27 about the implant axis 35. The direction of rotation is immaterial provided the shaft 29 is essentially symmetrical about axis 35. The foreshortening caused by rotation is used to deduce the rotation and to effectively shrink or expand the boundaries 39 and 37 according to the other stored templates to provide an improved matching of the template. The deduced angle of the implant 27 may be used to generate a notification to the operator that the implant is being imaged at an angle perhaps different from that originally measured in a previous benchmark.

Identify bone

Regardless of the type of implant used, at this point the matrix of PBM values has a set of values which correspond only to bone and tissue, and these two must be discriminated. To determine the edge of the bone, a raw threshold determination, such as that used for finding the edge of the implant, was found not to be accurate due to wide variations in the bone densities of actual patients, particularly at the bone margins and, in some cases, in the middle. Therefore a more sophisticated technique was adopted which begins with an edge detection procedure. The whole process is illustrated in Fig. 4, which corresponds to step 54 of Fig. 2.

In step 90, a density distribution curve of the values over the entire curve is generated. This curve is a plot of

all PBM data values, regardless of location. The curve is examined at step 92 to find the first valley in the curve, which is the starting point for the threshold value to separate bone and soft tissue. This threshold is then used at step 94 to locate the approximate edges of the bone. The edges are then refined at step 96 through a process of locating where the change of PBM values between adjacent data points is large and still adjacent to the expected edge of the bone. Since the edge of the bone is expected to be contiguous, a median filter process is used at step 98 to finally adjust the bone edges. The edges thus defined are used to separate bone from soft tissue for the remainder of the analysis. Again a manual override is provided for the operator to correct for anomalous conditions.

Locate landmarks

As indicated by process block 56, up to six landmarks are identified from the bone edges and the prosthetic implant edges as previously described. The landmarks to be identified are illustrated in Fig. 5 and are: a) the lesser trochanter 100, b) the implant lip 102, c) the top of the implant 104, d) the medial edge 106 of the shaft of the implant, e) the lateral edge 108 of the shaft of the implant, and f) the center 110 of the shaft of the implant. These landmarks are located by comparative analysis of local data matrix values to identify the local value relationships that are characteristic of these landmarks. These landmarks

serve as fiducial points, as will be described, for ensuring that subsequent scans of the patient will be properly aligned and thus may be directly compared to other such scans.

In the preferred embodiment of this process, the most medial tip of the lesser trochanter 110 is used as the origin point of a coordinate system to divide the samples of the data matrix, by ray coordinates, into the five regions, as indicated in process step 70 of Fig. 2. The location of the lesser trochanter is defined by the system to be the medial bone edge that is farthest from the implant in a plane perpendicular from the implant edge. This is illustrated in Fig. 5 where a perpendicular line is drawn from the trochanter perpendicular to the implant edge, and the lesser trochanter is shown at 100. Also in Fig. 5, a horizontal dashed line is drawn on the scan line of the trochanter as well.

The implant lip 102 is defined as the first line of the scan (y-coordinate) where there is no bone found on the medial side of the implant. This is the point at which the inside edge of the implant exits the bone.

The top of the implant 104 is defined at the first line of the scan (y-coordinate) in which the lateral or outside edge of the implant boundary has an abrupt horizontal change.

The medial 106 and lateral 108 edge of the implant are

defined at the horizontal line (y-coordinate) of the trochanter. In the matrix of values, the position of the coordinates of the edges of the bone on the same scan line (the horizontal dashed line in Fig. 5) as the trochanter was defined are used. The shaft centerline 110 is defined as the point halfway in between the medial and lateral edge of the implant shaft.

The lesser trochanter, the medial edge, the lateral edge, and the centerline are all used for positioning the regions described below. The implant top and the tip of the implant are used for the forced nodes in the implant isolation and curve fitting routine already described above.

Locating regions

The fiducial points thus derived are then used to define the useful regions of interest for examination of bone density adjacent the implant, as illustrated at step 58 of Fig. 2. In the present instrument embodying the invention, at least four such regions are identified.

The first of these regions is a baseline region, which is intended to provide a set of samples that are free from artifacts and bone, and that may be used to standardize the PBM values from scan to scan despite variations in soft tissue, x-ray intensity, and detector sensitivity. The baseline region is defined beginning at the lesser trochanter. The medial edge of the baseline regions is defined as a vertical line located 1.5 cm medially from the

lesser trochanter. At the same horizontal position (the same y-coordinate), the lateral edge of the baseline region is defined to be 1.0 cm lateral from the lateral edge of the implant. The upper and lower (distal and proximal) edges of the baseline region are defined as 2 cm distal and proximal from the lesser trochanter, for a total vertical extent of 4 cm. A rectangular solid line is drawn on Fig. 5 illustrating the area of the baseline region.

A second region is a medial inferior region extending from the trochanter proximally by 2 cm and medial to the implant edge, and incorporating the area of bone located within that region. This region would thus lie within the baseline region, and would incorporate all the area of bone medial to the implant, inside the baseline area and below the lesser trochanter.

A third region is a medial superior region extending from the trochanter proximally 2 cm and medial to the implant edge. Again this region is in the baseline region, and would incorporate all the area of bone medial to the implant, inside the baseline area and above the horizontal of the lesser trochanter.

A fourth region is the first lateral region beginning at the horizontal (y-coordinate) level of the trochanter and proceeding proximally 2 cm on the lateral side of the implant. This area would thus be all the bone area lateral to the implant, inside the baseline area, and above the

horizontal to the trochanter.

A fifth region is the second lateral region beginning at the proximal edge of the last region and proceeding an additional 2 cm up or proximally. This last region would include an area of bone outside the baseline region, lateral to the implant edge, and extending 2 cm upward from the fourth region above.

Referring to process block 60, the baseline value is now calculated. A curve of the distribution of PBM values throughout the baseline region is made. An initial value is selected which is the most prevalent value in the curve, or the peak of the distribution. The initial value is adjusted by an iterative process converging onto the average value of the most common tissue in the region of interest. The region of interest here, the baseline region, was selected to be of such a size and location that soft tissue, i.e. not bone or implant, would be the prevalent tissue in the area.

Display

The data matrix may be displayed as a bone density image is represented in step 62 and sample display are shown in Figs. 8 and 9. The displays are composed of pixels whose coordinates on the display correspond to the coordinates of rays 16 associated with the samples pairs of the data matrix. The intensity of each pixel in the defined area of bone is made proportional to the PBM, and hence the BMD, along the corresponding ray 16. The pixels will thus

qualitatively delineate the edge 112 of the femur 26, and the boundaries 114 of different bone density, by their intensity. As referred to hereafter and by convention, the long axis of the femur 26, and hence the y-axis of the scan, is oriented vertically in the bone density image 122 with the proximal end of the femur 26 toward the top of the bone density image 122 and the distal end of the femur 26 toward the bottom of the bone density image 122 as would mirror a standing person.

The pixels having associated matrix elements with PBM values identified to the prosthetic implant are set equal to a background color to form a silhouette 116 of the prosthesis on the bone density image 122 readily distinguishable from the image of the femur 26. The pixels corresponding to elements of the data matrix along the edge between the prosthetic implant 27 and other tissue are shown on the display 42 as a red line (dotted on Figs. 8 and 9). These pixels and their corresponding data matrix elements will be termed the implant boundary 118. The operator may correct or adjust the implant boundary 118 as automatically defined above, by use of commands entered via the keyboard 38 and the trackball 40. Such adjustments, when necessary, will be performed in areas of the implant boundary 118 near sharp corners in the prosthetic implant 27 where the algorithmic curve fitting process has performed poorly.

The bone mineral composition ("BMC"), the total area of

bone and the BMD are calculated for each of these four above described regions of interest from the previously obtained PBM values: the medial and lateral, superior and inferior regions, all calculated relative to the baseline value. These areas are chosen to provide a general measure of bone characteristic that may be used for patient to patient comparison. For the purpose of this calculation, samples that fall only partially within the regions defined above only contribute a fraction of their calibrated PBM values to the measurements for the regions in proportion to the fraction of their total area within that region. These values are used to generate the shading information for the pixels of Figs. 8 and 9.

Note that all definition of regions of interest are calibrated from fixed fiduciary locations on the bone of the patient. This feature permits the instrument to be repeatedly used over time to measure changes in bone density at the fixed prescribed regions of interest.

Periprosthetic histogram

The BMD values near the prosthetic implant 27 may be displayed in histogram or profile form as will now be described. Referring to the flowchart of Fig. 6, a density histogram may be prepared for the femur 26 having the prosthetic implant 27. The density histogram is described in conjunction with the display illustrated in Fig. 8.

At process step 112, a measurement boundary 126 (shown

in Fig. 8) offset from the medial and lateral edges of the prosthetic implant 27 is identified. The measurement boundary 126 is set equal to the y-coordinates of the implant boundary 124, the definition of which was previously described, with a predetermined horizontal width added to x-coordinates of the implant boundary 124. If desired, the measurement area can be offset from the implant boundary, so that the measurement area effectively includes the area between, for example, 3 and 10 mm away from the implant edge, rather than the measuring beginning at the implant boundary edge, i.e. from 0 to 10 mm.

Referring to Fig. 8, the measurement boundary 126 is displayed on the bone density image 122 by a red line (dotted in Fig. 8) at the coordinates of the display corresponding to the y-coordinates of the matrix elements of the measurement boundary 126. The width of the measurement boundary 126 from the implant boundary 124 may vary between 2 to 10 mm, as selected by the operator. One measurement boundary 126 is associated with each of the medial and lateral implant boundaries 124 and is horizontally extending in a direction away from the prosthetic implant 27. If desired, but not shown in Fig. 8, the measurement area can be offset horizontally from the implant edge a distance of up to 3 mm.

A series of vertically adjacent and horizontally extending segments may be defined within the zone between

the measurement and implant boundaries 126 and 124, following the convention that the y-axis of the data matrix is vertical and the x-axis is horizontal. Each of these segments may contain from 1 to 10 samples or scan lines of the data matrix and as wide as the number of samples contained between the measurement and implant boundaries 126 and 124. The average BMD value for each segment is calculated at process block 114. At process block 116 the calculated values of BMD are plotted on a histogram 130 shown in Fig. 8, having average BMD on one axis and on the other axis distance from a reference point corresponding approximately to distance along the prosthetic implant 27 as a result of the alignment of the prosthetic implant 27 with the y-axis. One histogram 130 is created for the medial side of the prosthetic implant 27 and one for the lateral side of the prosthetic implant 27. The two histograms 130 are arranged to share their y-axis axes to provide ready comparison of the medial and lateral sides and hence to indicate visually symmetrical stress effects as have been described together to give an indication of the periprosthetic bone quality.

Two horizontal marker lines 132 superimposed on the bone density image 122 at arbitrary y-axis values, determined by the operator and on the corresponding y-axis values of the histograms 130, may be used to identify a number of segments. The average bone density value of the

segments so identified may be computed and displayed numerically on display 42. The index numbers of the scan lines between the marker lines 132 as referenced from the origin point are also displayed. Thus, the average bone density over a given length of the interface between the femur 26 and the prosthetic implant 27 may be quantified at any given location as desired by the operator.

Trans-prosthetic Profile

Alternatively, a profile of bone density may be generated for elements of the data matrix along one scan line. Referring to the flowchart of Fig. 7 and shown in the profile display of Fig. 9, a single horizontal marker line 132 of a predetermined height may be used to identify a single selected scan line of data in the data matrix at process step 70. This data is plotted as a profile 134 at that selected height or location, by process step 72, showing BMD versus x-axis position, where the x-axis, as has been described, is directed so that the profile is trans-prosthetic. The implant itself is not shown in the display of Fig. 9. Both the lateral and medial sides of the scan line are shown in the profile 134, and the vertical location of the profile 134 is determined at process step 74 to be the BMD at each location. The process step 76 indicates that the display of Fig. 9 is generated and produced on the display 42. A pair of markers 136 and 138 may be positioned along and perpendicular to the x-axis axes of the profile

134 to allow the operator to measure absolute distance from the medial or lateral edge of the prosthetic implant 27 to that marker 136 or 138, and hence to that portion of the profile 134. Process step 78 represents the step of displaying the markers. The absolute position of the markers is shown in numerical form on display 42 by process block 80. This quantitative measure aids in evaluating bone resorption at specific locations along the implant, a measurement that was previously performed with radiographs and a ruler and with considerably less accuracy.

Although the above description of the trans-prosthetic profile is described with respect to a single scan line, it should be understood that more than one scan line could be in the profile region. If this is the case, the method is followed as above except that a mean is calculated of the values in the scan lines in the region and the mean values are presented in the display.

The above description has been that of a preferred embodiment of the present invention. It will occur to those who practice the art that many modifications may be made without departing from the spirit and scope of the invention. For example, the invention is equally applicable to other types of bone implants such as those used for the replacement of knee joints, where postoperative evaluation of the implant should be performed. In order to apprise the public of the various embodiments that may fall within the

scope of the invention, the following claims are made.

We claim:

1. A method of evaluating bone quality in a patient having a substantially radiolucent prosthesis implanted in a bone, the prosthesis having at least one edge and having radiographically detectable reference markers, the method 5 comprising the steps of:

collecting bone mineral density data over at least two dimensions, including portions of the prosthesis holding the reference markers, by means of a body penetrating digital imaging instrument, to generate a matrix of data values 10 wherein the value of each data element of the matrix is proportional to the mineral content of the bone at the corresponding location in the dimensions;

employing an electronic computer to:

(a) analyze the matrix of data values to identify the 15 location of the reference markers;

(b) determine the best fit of a stored template, having stored reference marker data and at least one stored edge, to the location of the reference markers;

(c) employ the best fit to identify an implant boundary 20 within the matrix of data values based on the stored template edge;

(d) establish a measurement boundary translated from the implant boundary by a predetermined distance along a translation axis;

25 (e) calculate bone mineral density within a plurality

of segments following the path of the measurement boundary to produce a set of segment values; and

(f) display a plot of segment values versus distance along the implant boundary.

2. The method of claim 1 including the step of analyzing the matrix of values to identify a fiducial point with respect to the bone and referencing an origin of the plot of segment values to the fiducial point.

3. The method of claim 1 wherein the implant has opposed medial and lateral edges and where the stored template provides a medial and lateral edge, wherein:
 - step (c) establishes a medial and lateral implant boundary based on the medial and lateral template edges;
 - step (d) establishes a medial and lateral measurement boundary translated by predetermined distances along a translation axis from the medial and lateral implant boundary; and
10. step (e) calculates bone mineral density within a plurality of segments following the path of the medial and lateral measurement boundaries; and wherein
 - step (f) displays plots of segment values versus distance along the medial and lateral measurement boundaries
15. with segment values plotted along first axes and distance along the implant boundary plotted along the second axes, where the second axes are aligned so that the corresponding medial and lateral segment values are aligned for comparison.

4. The method of claim 1 including the additional step of:

- (g) calculating average bone mineral density of a predetermined number of segments along the implant boundary.

5. A method of evaluating bone quality in a patient having a substantially radiolucent prosthesis implanted in a bone, the prosthesis having at least one edge and having radiographically detectable reference markers, the method
5 comprising the steps of:

collecting bone mineral density data over at least two dimensions, including portions of the prosthesis including the reference markers, by means of a body penetrating digital imaging instrument, to generate a matrix of data
10 values wherein the value of each data element of the matrix is proportional to the mineral content of the patient at the corresponding location in the dimensions;

employing an electronic computer to:

(a) analyze the matrix of data values to identify the
15 location of the reference markers;

(b) determine the best fit of a stored template, having stored reference marker data and at least one stored edge, to the location of the reference markers;

(c) employ the best fit to identify an implant boundary
20 within the matrix of data values based on the stored template edge;

(d) establish a measurement boundary translated from the implant boundary by a predetermined distance along a translation axis;

25 (e) identifying a position of a fiducial point in the bone within the matrix of data elements;

(f) calculate bone mineral density within a plurality of segments following the path of a measurement axis having a predetermined distance and orientation with respect to

30 said fiducial point and removed from the implant as defined by the measurement boundary; and

(g) display a plot of segment values versus distance along the measurement axis.

6. An apparatus to evaluate bone quality in a patient having a substantially radiolucent prosthesis implanted in a bone, the prosthesis having at least one edge and having radiographically detectable reference markers, the apparatus
5 comprising:

a radiation source and detector for collecting bone mineral density data over at least two dimensions, including portions of the prosthesis holding the reference markers to generate a matrix of data values wherein the value of each
10 data element of the matrix is proportional to the mineral content of the bone at the corresponding location in the dimensions;

an electronic computer operating according to a stored program so as to:

15 (a) analyze the matrix of data values to identify the location of the reference markers;

(b) determine the best fit of a stored template, having stored reference marker data and at least one stored edge, to the location of the reference markers;

20 (c) employ the best fit to identify an implant boundary within the matrix of data values based on the stored template edge;

(d) establish a measurement boundary translated from the implant boundary by a predetermined distance along a

25 translation axis;

(e) calculate bone mineral density within a plurality

of segments following the path of the measurement boundary to produce a set of segment values; and

(f) display a plot of segment values versus distance
30 along the implant boundary.

7. The apparatus of claim 6 wherein the stored program includes the step of analyzing the matrix of values to identify a fiducial point with respect to the bone and referencing an origin of the plot of segment values to the
5 fiducial point.

8. The apparatus of claim 6 wherein the implant has opposed medial and lateral edges and wherein the stored template provides a medial and lateral edge, wherein the stored computer program is such that:

- 5 step (c) establishes a medial and lateral implant boundary based on the medial and lateral template edges;
- step (d) establishes a medial and lateral measurement boundary translated by predetermined distances along a translation axis from the medial and lateral implant
10. boundary; and
- step (e) calculates bone mineral density within a plurality of segments following the path of the medial and lateral measurement boundaries; and wherein
- step (f) displays plots of segment values versus
15. distance along the medial and lateral measurement boundaries with segment values plotted along first axes and distance along the implant boundary plotted along the second axes, wherein the second axes are aligned so that the corresponding medial and lateral segment values are aligned
20. for comparison.

9. The apparatus of claim 6 wherein the stored computer program also:

- (g) calculates average bone mineral density of a predetermined number of segments along the implant boundary.

10. An apparatus to evaluate bone quality in a patient having a substantially radiolucent prosthesis implanted in a bone, the prosthesis having at least one edge and having radiographically detectable reference markers, the apparatus
5 comprising:

a radiation source and detector for collecting bone mineral density data over at least two dimensions, including portions of the prosthesis including the reference markers, to generate a matrix of data values wherein the value of
10 each data element of the matrix is proportional to the mineral content of the patient at the corresponding location in the dimensions;

an electronic computer operating according to a stored program so as to:

15 (a) analyze the matrix of data values to identify the location of the reference markers;

(b) determine the best fit of a stored template, having stored reference marker data and at least one stored edge, to the location of the reference markers;

20 (c) employ the best fit to identify an implant boundary within the matrix of data values based on the stored template edge;

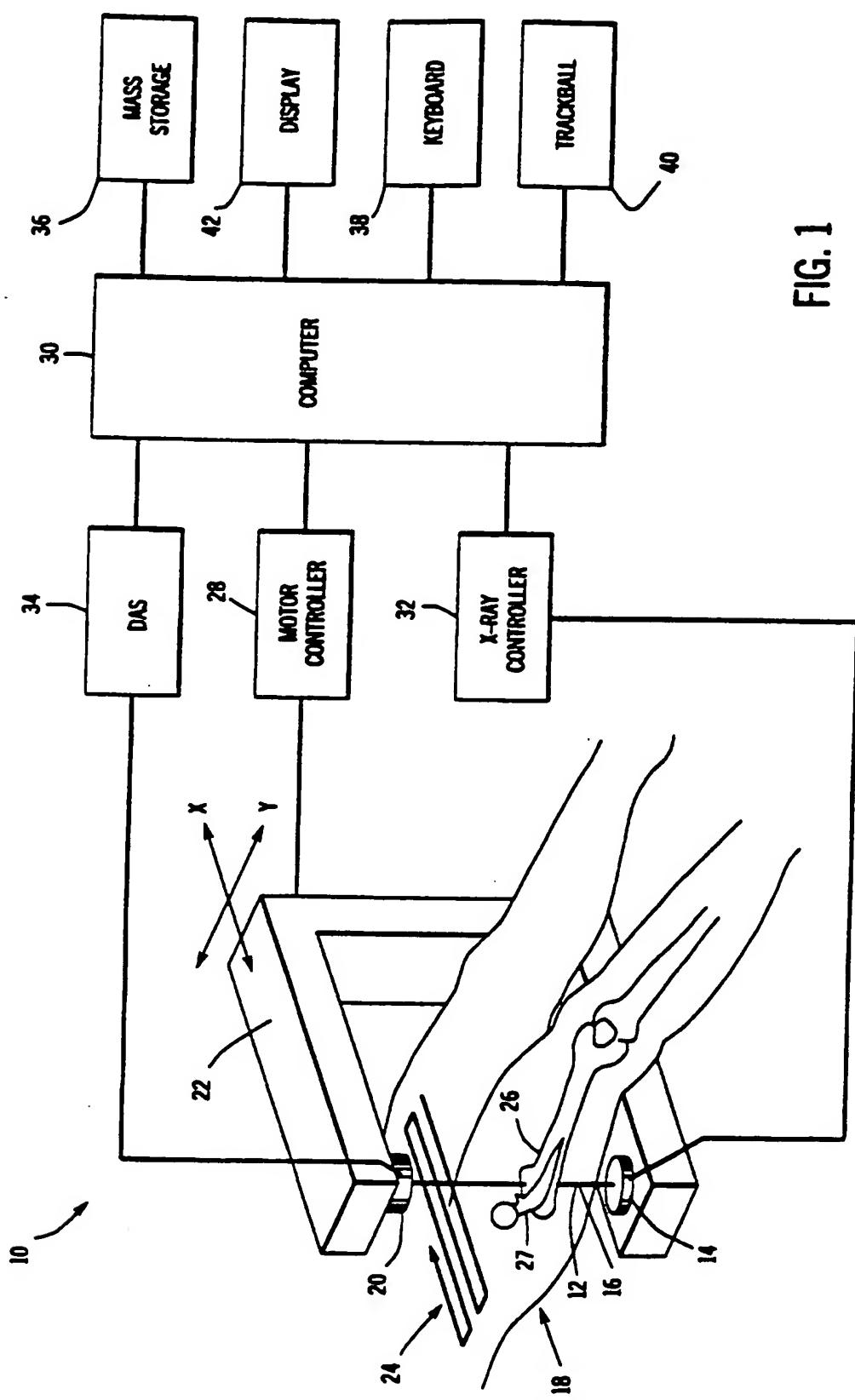
(d) establish a measurement boundary translated from the implant boundary by a predetermined distance along a
25 translation axis;

(e) identifying a position of a fiducial point in the

bone within the matrix of data elements;

30 (f) calculate bone mineral density within a plurality of segments following the path of a measurement axis having a predetermined distance and orientation with respect to said fiducial point and removed from the implant as defined by the measurement boundary; and

(g) display a plot of segment values versus distance along the measurement axis.



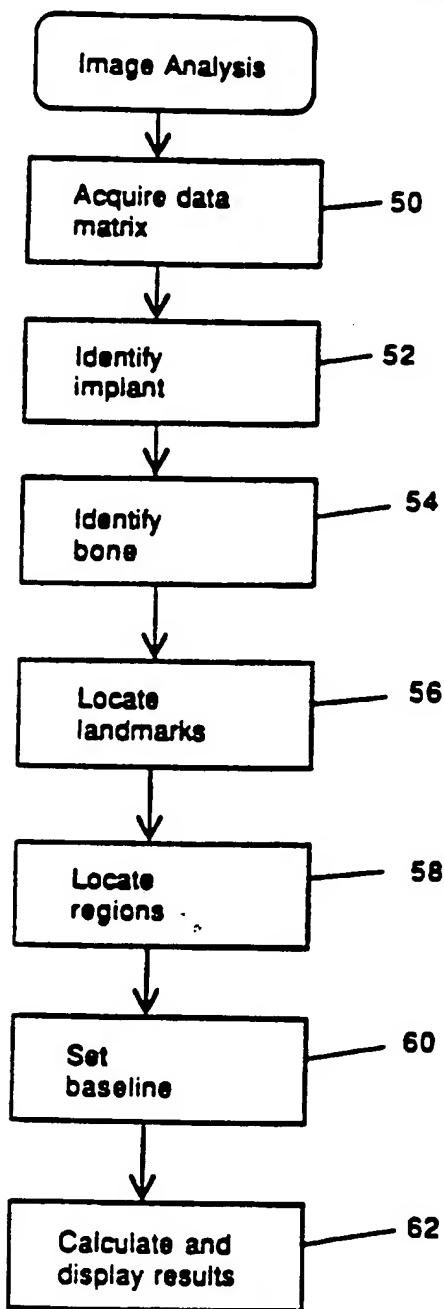


FIG. 2

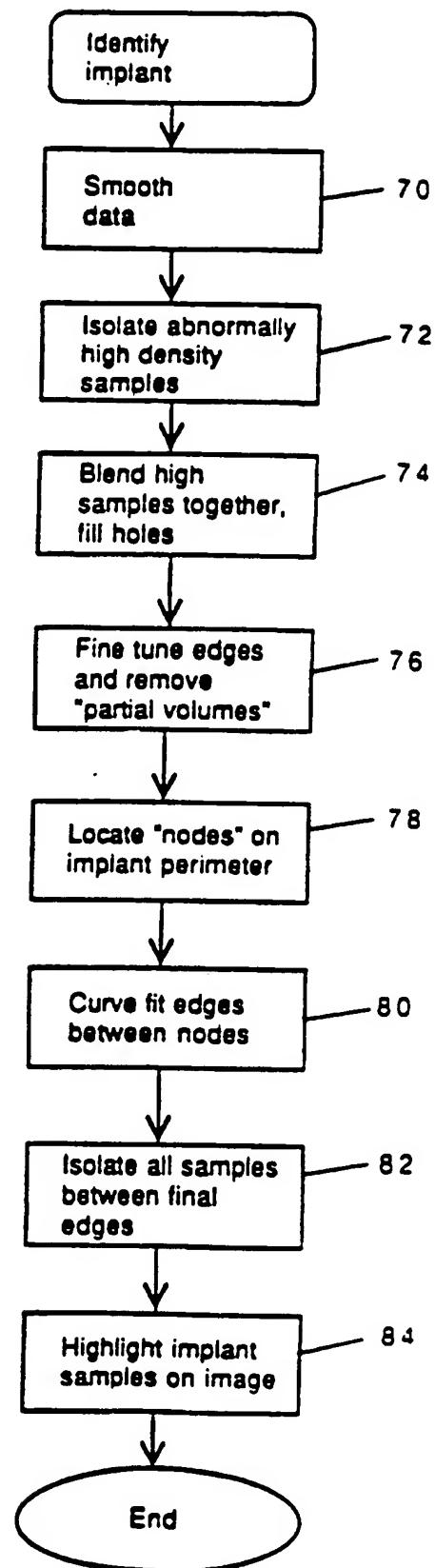
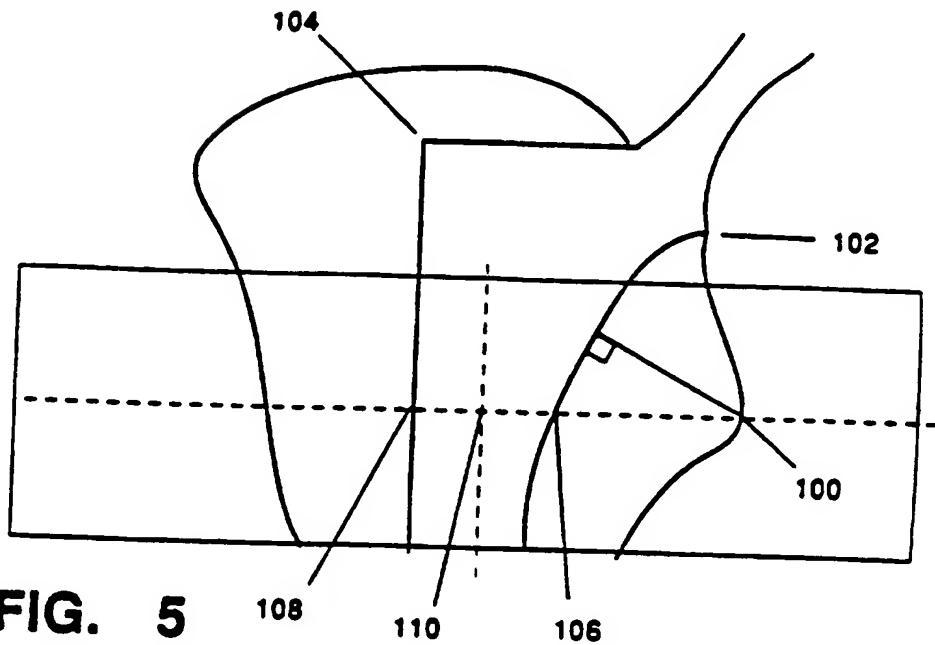
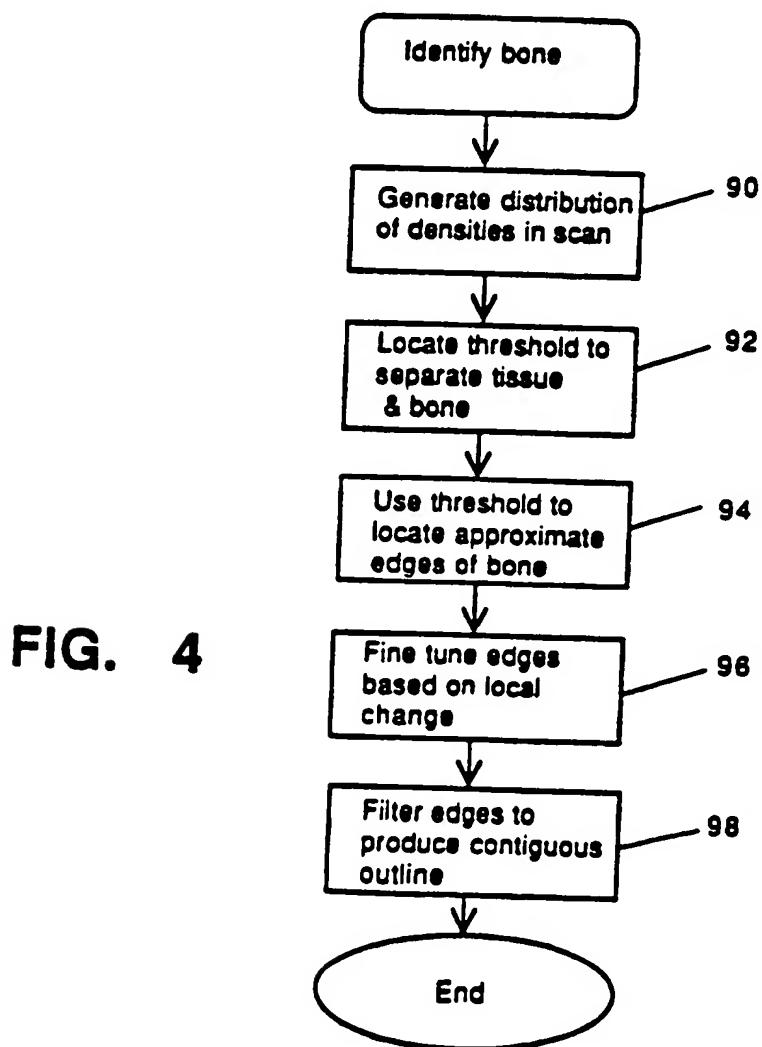


FIG. 3

**FIG. 5**

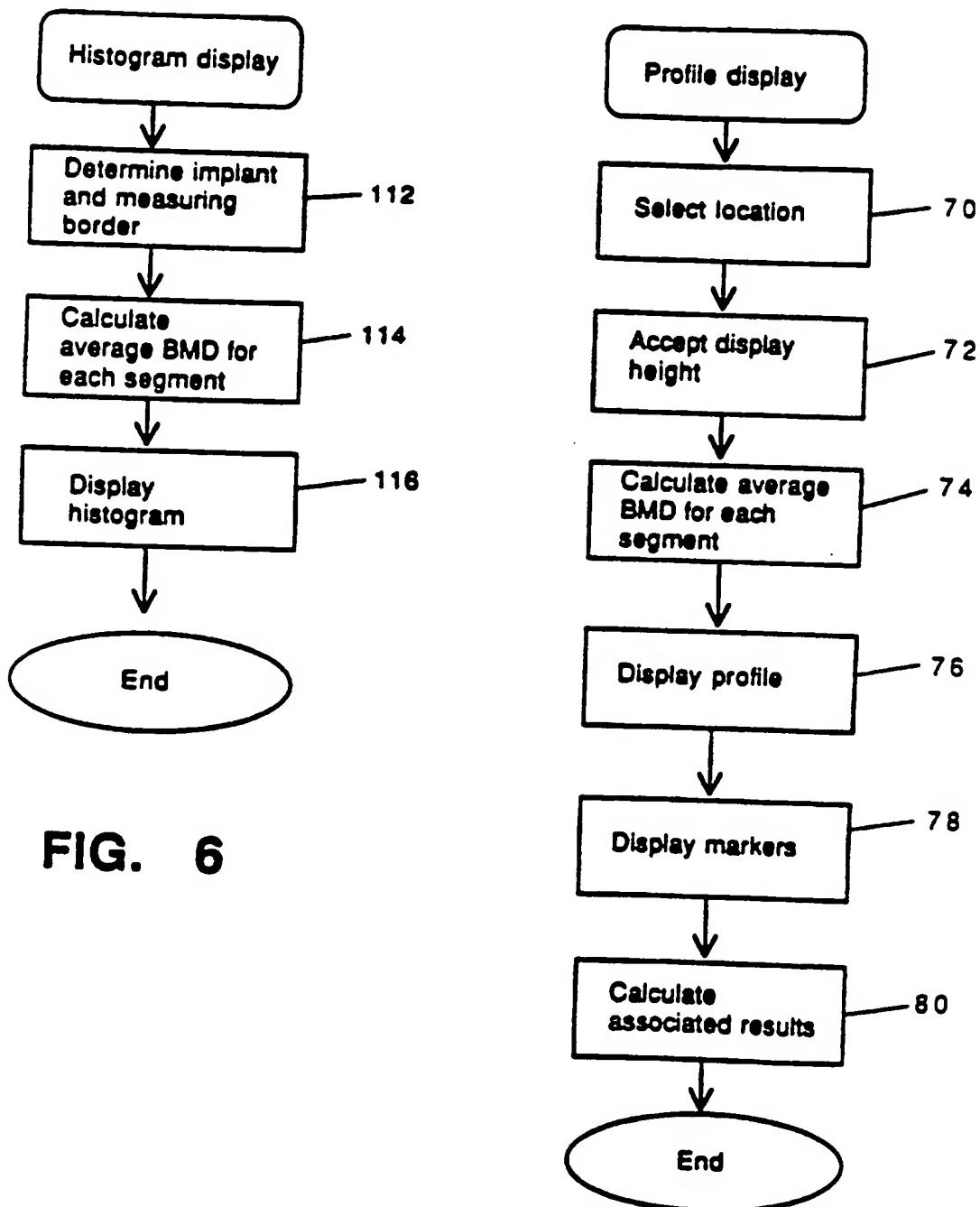
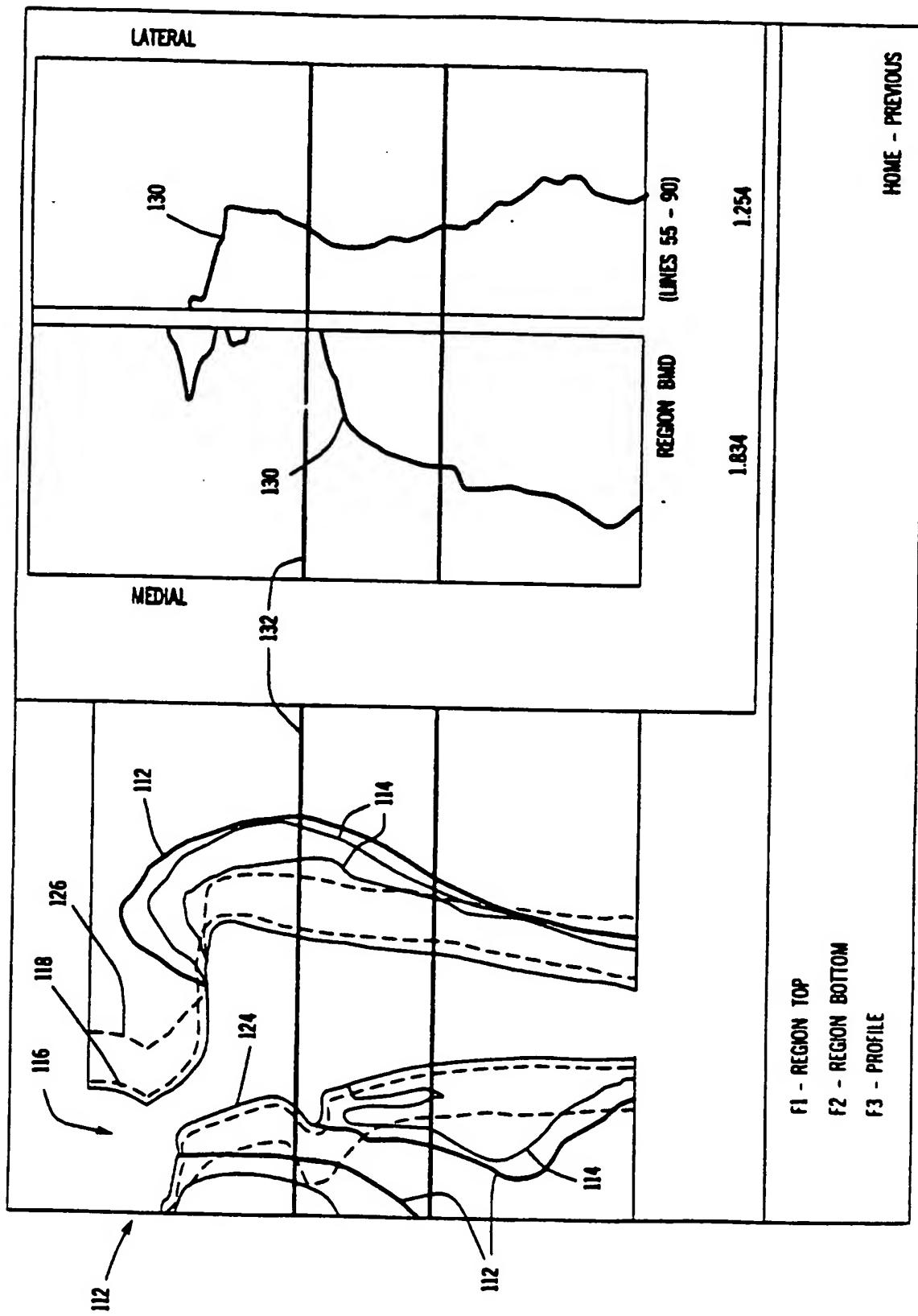
**FIG. 7**

FIG. 8



6/7

FIG. 9

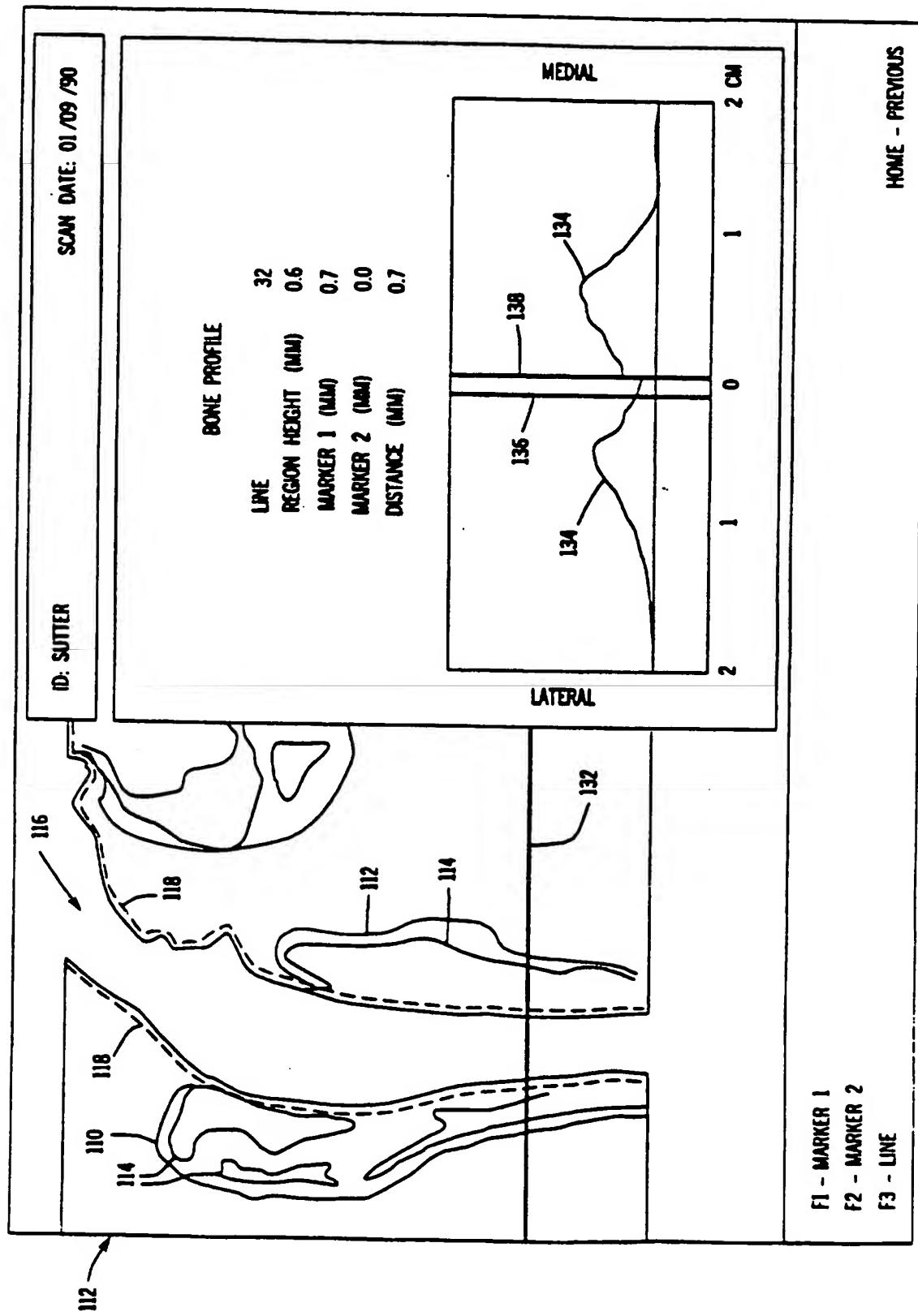


FIG. 10

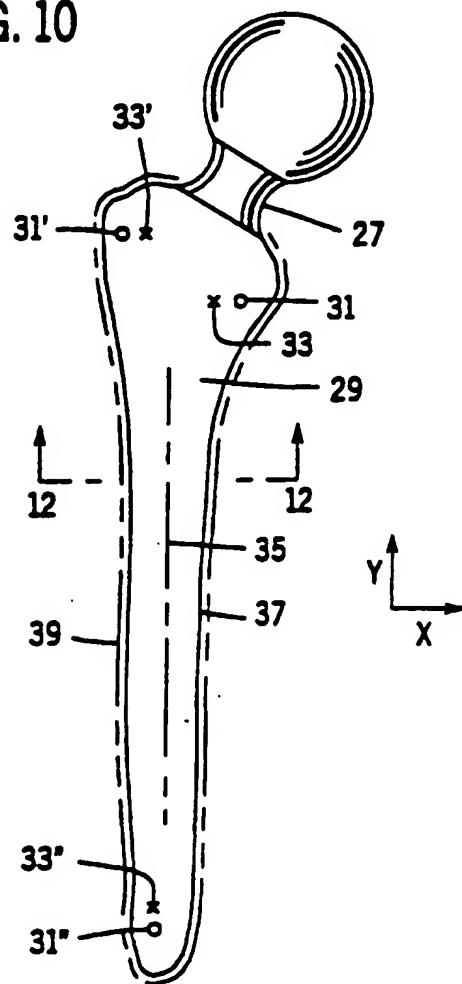
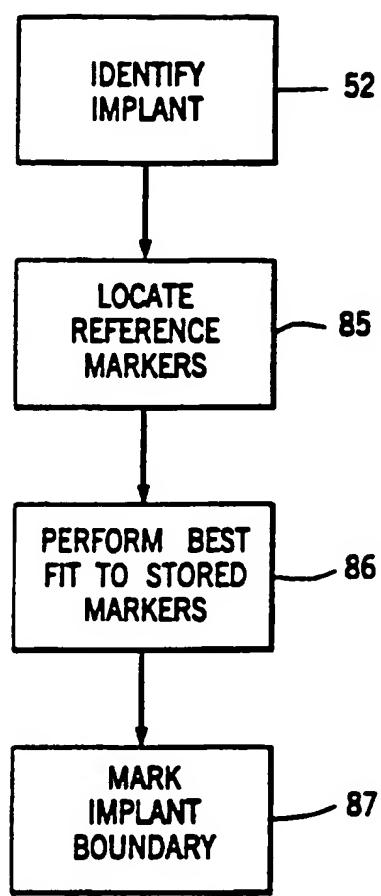


FIG. 11

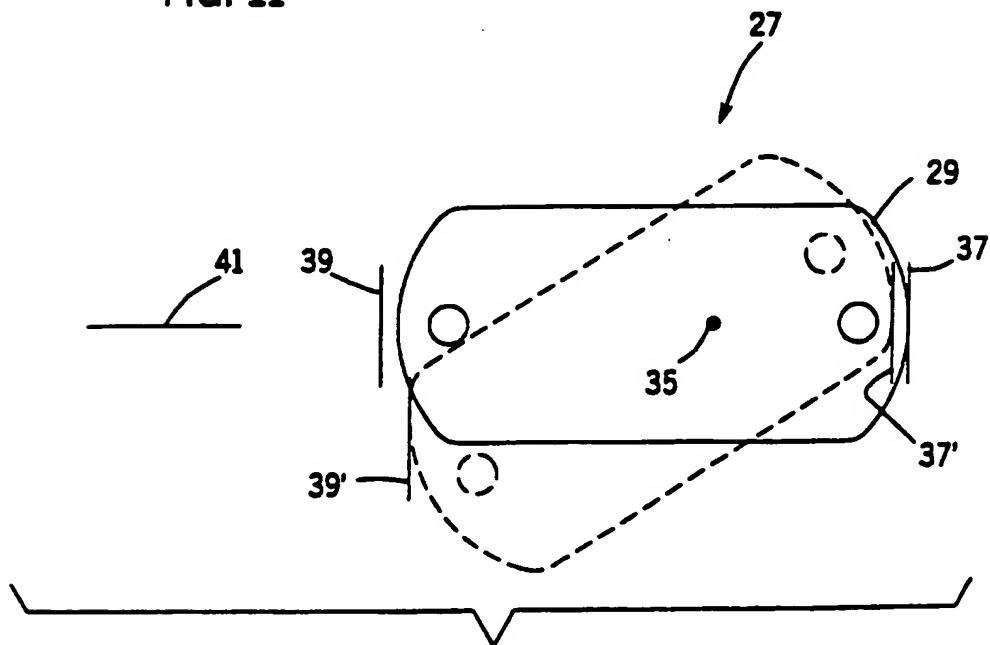


FIG. 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/00950

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61B 5/00, 6/00; A61F 2/28
US CL : 128,653.1; 378/89; 623/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/653.1, 661.03; 250/358.1; 378/4, 89, 90; 606/76, 77; 623/16

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 5,306,306, (BISEK ET AL.), 26 April 1994. See the entire document.	1-10

Further documents are listed in the continuation of Box C.

See patent family annex.

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Date of the actual completion of the international search

05 APRIL 1995

Date of mailing of the international search report

20 APR 1995

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